Section 6 510(k) Summary of Safety and Effectiveness

510(k) Summary of Safety and Effectiveness

JUN 27 2012

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	PolyRemedy, Inc.
TRADE NAME:	Poly FIT™+ Absorbing Antimicrobial Dressings (OTC) Poly FIT™+ High Absorbing Antimicrobial Dressings (OTC)
COMMON NAME:	Wound Dressing
CLASSIFICATION NAME:	Dressing, Wound, Drug
DEVICE CLASSIFICATION:	Unclassified (preamendment)
PRODUCT CODE	FRO
PREDICATE DEVICES:	Poly FIT™+ High Absorbing Antimicrobial Dressings (K092351) Kendall Kerlix AMD Antimicrobial Gauze Dressing (OTC) (K070653) Convatec Aquacel Ag Hydrofiber Antimicrobial Dressings (K080383)

Substantially Equivalent To:
PolyFIT+ Absorbing Antimicrobial Dressings are substantially equivalent in intended use, principal of operation and technological characteristics to the legally marketed PolyFIT Absorbing Antimicrobial Wound Dressing (K092351) and the Kendall Kerlix AMD Antimicrobial Wound Dressing (K070653) and the Convatec Aquacel Ag Hydrofiber Antimicrobial Dressings (K080383).

Description of the Device Subject to Premarket Notification:

PolyFIT+ Absorbing Antimicrobial Dressings are soft, sterile dressings designed for the management of exudating wounds and are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are made of synthetic, hydrophilic, fibers embedded with a 0.3% concentration of Polyhexamethylene Biguanide (PHMB).

PolyRemedy employs an electrospinnng process to manufacture the ingredients: polyethylene oxide (PEO), polyethylene-co-vinyl-alcohol (EVOH), polycaprolactone (PCL) and PHMB into fibers, forming consistent and congruent dressings.
Within the PolyFIT+ Absorbing Antimicrobial Dressings, the PEO gelling fibers are supported by the EVOH and PCL fibers for structural integrity. While absorbing wound exudate, the fibers transform from a dry dressing into a fiber gelling dressing that rapidly absorbs excess exudate away from the wound surface and retains it in the dressing. When exudate is absorbed into the PolyFIT+ Absorbing Antimicrobial Dressing, the PHMB embedded in the fibers ensures that when bacteria come in contact with the PHMB molecule the outer cell wall of the bacteria is disrupted,

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resulting in leakage of cytoplasm and cell death. As a consequence, bacterial numbers decrease, replication ceases and mutation cannot occur.

Indication for Use:

For Over-the-Counter Use, PolyFIT™+ Absorbing Antimicrobial Dressings and PolyFIT™+ High Absorbing Antimicrobial Dressings may be used for minor abrasions, minor lacerations, minor cuts, minor scalds, and minor burns.

Indications for Use:

Under the supervision of a healthcare professional, PolyFIT™+ Absorbing Antimicrobial Dressings and PolyFIT™+ High Absorbing Antimicrobial Dressings may be used for the management of:

> PolyFIT+ Absorbing Antimicrobial Dressings are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are for use as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3rd degree burns or for dry wounds.

Technical Characteristics:

PolyFIT+ Absorbing Antimicrobial Dressings have similar physical and technical characteristics to the predicate devices.

Non-Clinical Performance Data:

All necessary verification and validation testing has been performed for the PolyFIT+ Absorbing Antimicrobial Dressings to assure substantial equivalence to the predicate devices.

Clinical Data:

This submission does not rely on clinical data to determine substantial equivalency to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and effectiveness information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the PolyFIT+ Absorbing Antimicrobial Dressings are determined by PolyRemedy to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 27 2012

Polyremedy, Incorporated
% Gary Mocnik and Associates
Mr. Gary Mocnik
49 Coastal Oak
Aliso Viejo, California 92656

Re: K121522
Trade/Device Name: PolyFit™+ Absorbing Antimicrobial Dressings (OTC)
Regulation Name: Unclassified
Product Code: FRO
Dated: May 15, 2012
Received: May 23, 2012

Dear Mr. Mocnik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 — Indications for Use Statement

Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): 121522

Device Name: **PolyFIT™+ Absorbing Antimicrobial Dressings and PolyFIT™+ High Absorbing Antimicrobial Dressings**

For Over-the-Counter Use, PolyFIT™+ Absorbing Antimicrobial Dressings and PolyFIT™+ High Absorbing Antimicrobial Dressings may be used for minor abrasions, minor lacerations, minor cuts, minor scalds, and minor burns.

Indications for Use:

Under the supervision of a healthcare professional, PolyFIT™+ Absorbing Antimicrobial Dressings and PolyFIT™+ High Absorbing Antimicrobial Dressings may be used for the management of:

PolyFIT+ Absorbing Antimicrobial Dressings are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are for use as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, or for 3rd degree burns.

OR

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter Use__X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121522